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_	IN THE UNITED STATES DISTRI
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IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation	No. 2:15-MD-02641-DGC
	DEFENDANTS C. R. BARD, INC. AND BARD PERIPHERAL VASCULAR, INC.'S MOTION TO
	EXCLUDE THE OPINIONS OF ROBERT M. MCMEEKING, PH.D, AND SUPPORTING
	MEMORANDUM OF LAW
	(ASSIGNED TO THE HONORABLE DAVID G. CAMPBELL)
	(ORAL ARGUMENT REQUESTED)

INTRODUCTION

Pursuant to Federal Rule of Evidence 702, and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) and its progeny, Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively "Bard"), respectfully move to exclude certain expert opinion testimony offered by Robert M. McMeeking, Ph.D.

11115 MILEY & DCA LLP. LLP. Atlanta, GA 30363 (404) 322-6000 ("Dr. McMeeking"), a professor of structural materials and mechanical engineering. Bard's Motion is supported by the following Memorandum of Points and Authorities and any oral argument the Court may entertain.

MEMORANDUM OF POINTS AND AUTHORITIES

Bard seeks to exclude the following opinions of Dr. McMeeking:

- 1. That Bard did not go far enough to reduce the risks with its IVC filters;
- 2. That Bard's communications with the FDA failed to fully communicate relevant information regarding its IVC filters;
- 3. That rates of complications in Bard filters are "dangerous"; and
- 4. The Simon® Nitinol Filter is a safer, alternative product.

Bard seeks to exclude these opinions on the grounds that Dr. McMeeking is either not qualified to testify to these opinions, has failed to provide reliable, scientific methodology to support these opinions, and/or relies solely upon the work of other experts, without independently verifying that work. These opinions amount to unreliable, unsubstantiated conjecture that will not assist the trier-of-fact in determining the issues in this case.

ARGUMENT AND CITATION OF AUTHORITY IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE DR. MCMEEKING

For an expert's opinion to be admissible under Federal Rule of Evidence 702, the Court must find that "(1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case." Rule 702 incorporates principles established in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), in which the Supreme Court charged trial courts with a gatekeeping role to "ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable." *Id.* at 589. Ultimately, the objective of *Daubert* is "to make certain that an expert . . . employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999). The proponent of expert testimony must demonstrate admissibility by a

preponderance of proof. *Daubert*, 509 U.S. at 592 n. 10; *Lust By & Through Lust v. Merrell Dow Pharm.*, *Inc.*, 89 F.3d 594, 598 (9th Cir. 1996). And "nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence which is connected to existing data only by the *ipse dixit* of the expert." *General Electric Co. v. Joiner*, 522 U.S. 136, 146 (1997). Under the above *Daubert* standard, the opinions discussed in this Motion are unreliable.

A fundamental requirement of Rule 702 is that the proposed scientific/technical testimony "assist the trier of fact to understand the evidence or to determine a fact in issue." The Ninth Circuit has found that "[f]ederal judges *must . . . exclude* proffered scientific evidence under Rules 702 and 403 unless they are convinced that it speaks clearly and directly to [the] issue in dispute in the case, and that it will not mislead the jury." *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1321 n.17 (9th Cir. 1995) (emphasis added).

The four opinions of Dr. McMeeking identified above will not assist the trier-of-fact and should be excluded. *See e.g., U.S. v. Frazier*, 387 F.3d 1244, 1262-63 (11th Cir. 2004) (also noting that expert opinion is not helpful to the trier of fact "when it offers nothing more than what lawyers for the parties can argue in closing arguments"); *In re: Trasylol Prod. Liab. Litig.*, 709 F. Supp. 2d 1323, 1346 (S.D. Fla. 2010) (excluding testimony concerning regulatory history, FDA correspondence, and internal company documents, noting that the issues should be presented to the jury directly, not through an expert who "regurgitates them and reaches conclusory opinions . . . and invades the province of the jury."); *In re: Baycol Prods. Litig.*, 532 F. Supp. 2d 1029, 1067 (D. Minn. 2007) (excluding testimony as "lay matters" and "conclusory statements about questions of fact masquerading behind a veneer of technical language" where plaintiffs proffered an expert to opine that Bayer ignored its toxicologists' concerns about Baycol's steep doseresponse curve as it concerned Baycol's safety profile); *In re: Rezulin Prod. Liab. Litig.*, 309 F. Supp. 2d 531, 555 (S.D.N.Y. 2004) (excluding expert testimony concerning the alleged downplaying of hepatotoxic effects of Rezulin in the published literature based on

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internal documents, memos, and e-mails, finding that the issues constituted "lay matters" and would amount to arguing from the witness stand).

1. Bard did not go far enough to reduce the risks with its IVC filters.

Dr. McMeeking's Rule 26 Report cites "GHTF Essential Principles of Safety and Performance" which state, in part, that manufacturers should "eliminate risks as far as reasonably practicable through inherently safe design and manufacture." (Ex. A, McMeeking 3/3/17 Rule 26 Report, at 5.) When questioned at his deposition about this opinion, Dr. McMeeking stated that Bard failed to reduce risks in its IVC filters as much as was reasonably practicable under engineering principles.

> Is it your opinion that Bard failed to reduce as far as reasonably practicable the remaining risks by taking adequate protection measures?

A In certain of the designs of the filters those risks, in my opinion, were not reduced to the extent practicable, and I would say that that applies to all of the models that we are discussing in the -- in the present case.

And which risks do you identify -- that you have an opinion that Bard failed to reduce?

A The risks of tilting, perforation, migration and fracture by fatigue.

(Ex. B, McMeeking Dep. Tr., 23:3-23, July 6, 2017.)

For example, Dr. McMeeking further claims that Bard could have reduced risks in its IVC filters by electropolishing them before it brought the Eclipse® to market in 2010. However, as to both of his general opinions -- that Bard could have done more to reduce risk in its IVC filters, and his few specific examples of what he believes Bard could have done to reduce some risks in its IVC filters -- Dr. McMeeking admits he has used no research, no investigation, no testing, or any sort of accepted scientific methodology to

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determine what was reasonably practicable for Bard to have done in order to reduce risks associated with its IVC filters, (Id. at 23:24-24:11; 28:8-30:6), and, at best, relies on Dr. Ritchie to provide any basis for these opinions. (*Id.* at 30:7-32:4.) In addition to the electropolishing example, Dr. McMeeking also opines that Bard could have developed caudal anchors and penetration limiters on its filters sooner than it did through the introduction of the Meridian® filter in 2011. This opinion, however is based solely on the fact that Bard "eventually" added those design features; he provides no scientific verification, no specific citation to any Bard internal documents suggesting caudal anchors and penetration limiters could have been incorporated into Bard filters sooner, and knows of no filter manufacturer who added anchors or limiters sooner than Bard did. (Id. at 32:6-33:23.) Moreover, though Dr. McMeeking criticizes Bard for not developing anchors and limiters, Dr. McMeeking does not even have an opinion whether the anchors or limiters on Bard's Meridian or Denali[®] filter models would improve resistance to migration, tilt, perforation or fracture. (*Id.* at 130:2–19.) Without having done any work to determine whether these design changes would have reduced these risks, Dr. McMeeking cannot properly opine that Bard's evolutionary design of these filters failed as "reasonably practicable" efforts to minimize those risks. And, in fact, he testified that the changes may have decreased some risks. (Id.) Dr. McMeeking further states that Bard could have "redesigned the configuration of its filters" to improve risks associated with them. (Id. at 32:6-21.) As support for this opinion, Dr. McMeeking identifies changes in filter limb dimension, or using a different material instead of Nitinol, but he admits that he has not specifically examined in Bard filters how changes to the type of material used, diameter of limbs, shapes of limbs, and numbers of limbs would cause Bard's filters to perform better. (Id. at 34:9-36:22.) In addition, Dr. McMeeking admits that he has not developed any sort of prototype that demonstrates these changes would help Bard filters perform better. (*Id.* at 36:10-22.)

Despite acknowledging that anchors and limiters may well have helped to reduce risks in Meridian and Denali, Dr. McMeeking opines that Bard failed to reduce "as far as

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Those sorts of bald assertions, unmoored to any scientific analysis or methodology, are not admissible. The Rule 702 Advisory Committee states: "[t]he trial court's

gatekeeping function requires more than simply 'taking the expert's word for it." (*Id.* (citing *Daubert v. Merrell Dow Pharms. Inc.*, 43 F.3d 1311, 1315 (9th Cir.), *cert. denied* 516 U.S. 869, 116 S.Ct. 189, 133 L.Ed.2d 126 (1995)). In addition, "any step that renders [the expert's] analysis unreliable ... renders the expert's testimony inadmissible. This is true whether the step completely changes a reliable methodology or merely misapplies that methodology." *See In re Silicone Breast Implants Litig.*, 318 F.Supp.2d 879, 890 (C.D.Cal. 2004) (citing *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 745 (3d Cir.1994)).

In sum, Dr. McMeeking relies almost exclusively on his engineering credentials to offer conclusory statements about what Bard could have or should have done to limit risks with its filters, and when Bard should have taken such steps. Dr. McMeeking does not employ any scientific methodology or proffer any validated engineering basis to support those opinions. Dr. McMeeking is essentially asking the trier-of-fact to "take his word for it" because he is a professor of structural materials and mechanical engineering. This does not satisfy *Daubert* requirements. Therefore, his opinions are not reliable, or helpful to the trier-of fact, and they should be excluded.

2. Dr. McMeeking should not be permitted to opine that Bard's communications with the FDA failed to fully communicate relevant information regarding its IVC filters.

In his Rule 26 Report, Dr. McMeeking states "Bard was not frank and honest with the FDA in that the company did not fully inform the FDA of deficiencies that the G2 filter was exhibiting after implant." (Ex. A, McMeeking 3/3/17 Rule 26 Report, at 10.) When asked what he relies on to say that Bard was not "frank and honest with the FDA" he testified "I'm relying on Dr. Parisian for that opinion." (Ex. B, McMeeking Dep. Tr., 51:24–52:14, July 6, 2017.) However, Dr. McMeeking agrees that he has not reviewed the materials she reviewed. (*Id.*) Dr. McMeeking further opined that in "a couple of situations I've identified information that Bard gave to the FDA that was not correct." (*Id.* at 53:3–5.) While Dr. McMeeking may be qualified to give those opinions with respect to particular documents, he is not qualified to give the opinion, and has

provided no basis for the opinion, that any communications by Bard to the FDA were not "frank and honest." He does not possess the requisite foundation to conclude that Bard was not frank and honest with the FDA in its communications about IVC filters because, by his own admission, he "is not aware of what the FDA requires for these devices." (Ex. C, McMeeking Dep. Tr., 8:20-24, May 24, 2011.) And he does not know the full context and content of Bard's communications with the FDA, nor does he have any personal knowledge of the intent behind any of Bard's communications with the FDA. Accordingly, Dr. McMeeking should be precluded from giving any opinions about the sufficiency of Bard's communications with the FDA.

Courts have limited the scope of an expert's opinions where they venture into areas outside of their qualifications. *See e.g. Morritt v. Stryker Corp.*, 973 F. Supp. 2d 177, 188 (E.D.N.Y. 2013) (finding that a physician who had significant clinical experience with the medical device at issue went "well beyond the 'reasonable confines' of his clinical expertise" when offering opinions regarding biomedical engineering and material science, and that therefore the physician was not qualified to offer such opinions); *In re Silicone Breast Implants Litig.*, 318 F.Supp.2d at 902 (excluding opinions about the defendant's failure to conduct tests proffered by the plaintiff's expert, who had worked in quality control for a pharmaceutical company, published papers about medical devices, and holds patents on medical devices, on the grounds that such experience is insufficient foundational knowledge for offering opinions on testing); *Kruger v. Johnson & Johnson*

¹ Dr. McMeeking testified that he is not going to offer the opinion that Bard failed to comply with FDA regulations, and that "he will not interpret" certain information Bard provided to the FDA as Bard not being frank and honest with the FDA, "but, instead rely on Dr. Parisian for the overall assessment of that situation," (Ex. B, McMeeking Dep. Tr., 51:20-23; 51:24–52:14; 52:16-54:16, July 6, 2017.) However, it is unclear, based on the contradiction between Dr. McMeeking's Rule 26 Report and his deposition testimony, and his seeming reliance on Dr. Parisian to support that statement in his report, whether or not he is really offering this opinion. Thus, Bard respectfully requests a ruling from the Court on this point.

Professional, Inc., 160 F. Supp. 2d 1026, 1031 (S.D. Iowa 2001) (finding that a metallurgist was unqualified to offer design opinions regarding bone screws where he had no experience in the design of medical implants or any other medical devices); In re: Breast Implant Litigation, 11 F. Supp. 2d 1217, 1243-44 (D. Colo. 1998) (excluding design opinions of a scientist who held a Ph.D. in physical chemistry because being a chemist did not automatically qualify the witness on design issues when he lacked training and experience concerning design of breast implants).

Like the many courts that have excluded or limited the scope of opinions outside an expert's particular knowledge, the Court should exclude Dr. McMeeking's testimony about Bard's dealings with the FDA because he has no foundational knowledge to determine from any source that Bard was not frank and honest with the FDA.

3. Dr. McMeeking should not be permitted to opine that rates of complications in Bard filters are "dangerous".

During his MDL deposition, Dr. McMeeking testified that he will not give opinions on rates in these cases:

- Q Are you going to provide an opinion that Bard had a higher rate of any particular type of complication relative to other filters?
- A I'm not going to offer any opinion on the relative rates of complications of one filter versus another.
- Q What about one Bard filter versus another Bard filter?
- A I'm not going to give an opinion on that because I don't have enough data to truly assess the situation.
- (Ex. B, McMeeking Dep. Tr., 175:14–176:1, July 6, 2017.) However, Dr. McMeeking states on Pages 25 and 26 of his Rule 26 Report that he adopts Dr. Betensky's work as showing that Bard's retrievable filters have higher rates of complications.
 - Q When you say at the top of page 26 that she found -- you have to go back to 25, that she found statistically

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significant differences between the Recovery and the Simon Nitinol filter and then between the Simon Nitinol and the other Bard filters, what do you mean by 'statistically significant differences'?

THE WITNESS: That -- I mean that the differences in the numbers involved were put through tests by her that analyzed the statistical distributions and the differences and the comparisons and indicated, in the cases that I've identified, that these -- these deductions made from those statistics by her were meaningful in that they were identifying real differences in the performance and rates that were observed in the various filters.²

(*Id.* at 188:2–20.) Even though Dr. McMeeking opines that Dr. Betensky's statistics identified real differences in performance and rates that were observed in various filters, he also admits that he did not verify Dr. Betensky's data, or conduct a biostatistical analysis of his own. (Id. at 185:9–188:1.) Dr. McMeeking should be precluded from giving opinions on "dangerous" complication rates with Bard filters when he has done no independent analysis of that issue, and is not qualified to do so.

Dr. McMeeking justifies his opinions on "dangerous" complication rates by claiming that, with respect to Bard filters, there is medical literature that is "consistent with my assessment of the engineering considerations of the filter and that they tend to confirm that the filters are . . . dangerous." (*Id.* at 176:2–11.)

² Here, again, it is unclear, based on the contradiction between Dr. McMeeking's Rule 26 Report and his deposition testimony, and his seeming reliance on Dr. Betensky to support that statement in his report, whether or not he is really offering this opinion. Thus, Bard respectfully requests a ruling from the Court on this point as well.

³ Bard notes that Dr. Betensky does not opine in her report that Bard rates are "unacceptably high" relative to other retrievable filters. At most, her analysis was an attempt to show that Bard retrievable filters have a higher reporting risk ratio of

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Q	Okay. And so how are you using medical literature to	С
	support a conclusion of dangerousness?	

A Well, I'm observing in the medical literature that these complications occur with the filter and that those complications do present dangers to the -- to the patients, such as a fracture damaging an adjacent organ or a fracture leading to a limb that escapes into the heart or the lungs or the pulmonary artery.

(*Id.* at 176:2-177:9) Dr. McMeeking is not a medical doctor. (*Id.* at 222:11-12). And he does not know what the FDA requires of IVC filter manufacturers. (Ex. C, McMeeking Dep. Tr., 8:20-24, May 24, 2011.) There is no evidence in the records that Dr. McMeeking is a statistician. And he does not cite to specific medical literature demonstrating that Bard filters have dangerous complication rates, but rather testified that certain complications known to occur in all IVC filters, also occur in Bard filters, and are dangerous. (Ex. B, McMeeking Dep. Tr., at 176:2-177:9, July 6, 2017.)

Absent any specific qualifications, underlying data (which he was unable to cite), scientific methodology (which he has not undertaken), or independent verification of the work and conclusions of other experts (which he has not done), Dr. McMeeking's opinion on "dangerous" rates is speculative and should be excluded.

4. Dr. McMeeking should not be permitted to opine that the Simon® Nitinol Filter is a safer, alternative product.

A substantial portion of Dr. McMeeking's Rebuttal Rule 26 Report is spent comparing the Recovery® and G2® filters to the Simon Nitinol Filter ("SNF"), the permanent IVC filter sold by Bard. (Ex. E, McMeeking 5/11/17 Rule 26 Rebuttal Report, at 8-16.) His lengthy comparisons culminate with the opinion that "the design of the SNF

complications than the Simon Nitinol Filter ("SNF") which is not a retrievable filter. (Ex. D, Betensky 1/27/17 Rule 26 Report, at 1-16.)

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is substantially better than those of Recovery and G2 and similar Bard filters, with respect to migration, tilt, arm fracture and arm perforation . . . in sum, the SNF is a safer filter than the Recovery, G2 and similar Bard filters." (*Id.* at 16.)

Though Dr. McMeeking may be able to evaluate the design characteristics of an implantable medical device, here, he should not be permitted to make the leap from evaluating the design of the SNF filter to opining that the SNF is a safer filter than Recovery and G2 filters, respectively. While Bard retrievable filters may be implanted for permanent use, they also carry with them the important design characteristic of being able to be percutaneously retrieved. Courts have held that where the purported safer alternative product is not the functional equivalent of the allegedly defective product, it is not a safer alternative. See e.g., McCarthy v. Olin Corp., 119 F.3d 148, 155 (2d Cir. 1997) (finding that regular bullets were not a feasible alternative design for hollow-point bullets because the expansion mechanism of the hollow-point bullets "was an intentional and functional element of the design of the product."); Felix v. Akzo Nobel Coatings, 262 A.D.2d 447, 692 N.Y.S.2d 413 (2d Dept.1999) (holding the "functional difference" between an allegedly defective quick-drying, solvent-based lacquer and the plaintiff's purported, safer alternative, a water-based lacquer taking hours to dry, was fatal to the plaintiff's safer alternative argument). Given the above case law, it would be unduly prejudicial to Bard under Fed. R. Evid. 403 to allow Dr. McMeeking to offer this opinion when the SNF is functionally different than the Recovery, G2 and other Bard retrievable filters.

Also, to the extent that Dr. McMeeking relies on Dr. Betensky's opinions on Bard's "rates" to opine that SNF® is clinically safer than newer generation Bard filters, (Ex. B, McMeeking Dep. Tr., 188:2–20, July 6, 2017); (Ex. A, McMeeking 3/3/17 Rule 26 Report, at 25-26), courts have rejected opinions similar to Dr. McMeeking's opinion that Bard filters are dangerous based on a perceived number of complications. See e.g. Barban v. Rheem Textile Sys., Inc., No. 01 CV 8475, 2005 WL 387660, at *3-7 (E.D.N.Y. Feb. 11, 2005) (excluding expert testimony that the table saw in issue was inherently dangerous simply based on the number of injuries involving such table saws, where the

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expert had never designed any machines, never conducted studies or authored articles related to dry cleaning, undertook no utility studies, and offered no alternative designs).

Dr. McMeeking acknowledges that the SNF is a permanent filter, whereas, the other Bard filters are retrievable filters. (Ex. B, McMeeking Dep. Tr., 221:16-223:3, July 6, 2017.) Given the functional difference between the SNF and Bard retrievable filter models, under the cited case law, the SNF cannot amount to a safer alternative product here. In addition, Dr. McMeeking is not a medical doctor, (Id.) therefore, he is not qualified to offer the opinion that the SNF (a permanent filter that cannot be percutaneously retrieved) would be a safer alternative for any patient, and in particular for any of the five bellwether plaintiffs in this MDL. He cites to no testimony from any implanting doctor that the doctor selected a Bard retrievable filter for the patient without considering the retrievable function that accompanied the Bard filters.⁴ Consequently, Dr. McMeeking is not able to actually determine that an SNF filter was a safer alternative product for any individual plaintiff in this litigation.

CONCLUSION

Because Dr. McMeeking is unqualified to opine about the topics identified above, failed to use scientific methodology, and/or simply relied on opinions and analyses of other experts without verifying those opinions, his opinions are unreliable, will not help the jury determine the issues, and should be excluded.

⁴ Plaintiffs argue that in the case of Bellwether Plaintiff Carol Kruse, her implanter intended that the retrievable Bard filter he placed would be permanent in that patient, however, the implanter specifically testified that part of his consideration for use of the Bard filter in that patient was that it was retrievable in case it needed to be retrieved. (Ex. F, Smith Dep. Tr., 57:9-16; 68:16-20, April 4, 2017.)

1	DATED this 24th day of August, 2017.
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CERTIFICATE OF SERVICE

I hereby certify that August 24th 2017, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send e-mail notification of such filing to all attorneys of record.

s/Matthew B. Lerner Matthew B. Lerner